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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,648	04/13/2000	Zeling Cai	ORT1224	6532

7590 06/25/2003  
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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
09/548,648

Applicant(s)  
Cai et al.

Examiner  
G.R. Ewoldt, Ph.D.

Art Unit  
1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Apr 10, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 5, and 6 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, and 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

**DETAILED ACTION**

1. Claims 1, 3, 5, and 6 are pending and being acted upon.
2. Applicant's substitute drawings and response, filed 4/10/03, are acknowledged.
3. Applicant's new drawings have been found acceptable by the Examiner.
4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:  

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. Claims 1, 3, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gallimore et al. (1998, of record), for the reasons of record as set forth in Paper No. 22, mailed 1/10/03.

Applicant arguments, filed 4/10/03, have been fully considered but are not found persuasive. Applicant begins by summarizing the method disclosed in the specification as well as the method of the reference. It appears that Applicant's argument is that the fusion proteins of the instant claims are directly labeled whereas the conjugate of the reference is biotinylated and secondarily labeled with a PE labeled neutravidin. Apparently it is Applicant's position that this difference renders the claimed method patentably distinct.

It is the Examiner's position that various methods of labeling any protein of interest were well known in the art at the time of the invention. See, for example, U.S. Patent No. 5,858,777 (column 8, lines 14-29) wherein it is disclosed that various methods of labeling, e.g., fluorescent, phosphorescent, or radioactive, are interchangeable. Note that the reference also discloses that various methods for attaching a label, including secondary labeling of a biotinylated target, were also well known in the art. See also U.S. Patent No. 6,346,377 (paragraph spanning columns 5 and 6) which also discloses the interchangeability of various types of labels, including labels

comprising part of a fusion protein. Accordingly, it remains the Examiner's position that the invention of the instant claims is obvious in view of the prior art and that which would have been known to one of ordinary skill in the art at the time of the invention.

Applicant argues that reliance on the specification to establish obviousness is improper.

Indeed, said reliance would generally be improper. The Examiner only intended to point out that the specification itself, in the paragraph in question, disclosed three other U.S. Patents as representative of methods known in the art at the time of the invention. Additionally, the same paragraph also discloses that "It is also readily apparent to those of ordinary skill in the art that a variety of detectable markers, other than green fluorescent protein, can be fused to the MHC class I molecule, and are suitable for use in the methods of the present invention and can be linked to the MHC class I molecule by a wide variety of means." It would appear then that the method of labeling the MHC molecule was not intended to be the feature that renders the method of the claims patentably distinct as Applicant now argues.

6. The following is a new ground for rejection.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 3, 5, and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims are nonsensical in that they recite a method for the purification of T cells, yet the claims recite no purification step. Note that the method of the claims results only in the identification of T cells. Identification and purification comprise separate and distinct processes.

9. No claim is allowed.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (703) 308-9805. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196 or the Customer Service Center at (703) 308-0198.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone numbers are 703-872-9306 (before final) and 703-872-9307 (after final).



G.R. Ewoldt, Ph.D.  
Primary Examiner  
Technology Center 1600  
June 23, 2003